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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,488	11/14/2003	Dennis A. Grahn	STAN-334	1050
24353	7590	06/23/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			GIBSON, ROY DEAN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/714,488	<b>Applicant(s)</b> GRAHN ET AL.	
	<b>Examiner</b> Roy D. Gibson	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33,35 and 37-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 29-33,43 and 44 is/are allowed.
- 6) ☐ Claim(s) 1-17,19-21,25-27,35 and 37 is/are rejected.
- 7) ☐ Claim(s) 18,22-24,28 and 38-42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/12/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Formal Matters**

Claims 34, 36 and 45 were canceled by a Preliminary Amendment filed July 12, 2004. Therefore, claims 1-33, 35 and 37-44 are currently pending.

### ***Claim Objections***

Claim 43 is objected to because of the following informalities: in line 4, "o" should be "of" and in line 9, the examiner suggests "to" should be "of". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-14, 18-21, 26, 27, 35 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Kushnir et al. (6,685,731).

As to claims 1-5, 10-13, 18-21 and 26-27, Kushnir et al. disclose a method of transferring heat from a body portion of a mammal comprising the acts of:

determining a state of vasoconstriction or vasodilation in a portion of a body;

supplying heat to the portion of the body when vasoconstriction is determined;  
and

removing heat from the portion of the body when vasodilation is determined (col. 8, lines 34-62 and col. 10, line 29-col. 11, line 25); wherein the portion of the body is an arterial vascular anastomosis containing portion of the body (Figure 6 which shows a preselected portion of the neck of the patient is in contact with the heating/cooling device); wherein the act of determining vasoconstriction or vasodilation includes sensing a characteristic of the body associated with the state of vasoconstriction or vasodilation by measuring the core body temperature and the skin temperature or by measuring blood flow with echo or ultrasound Doppler (col. 5, lines 5-11).

Further to claim 8, it is inherent in the function of the mammalian body that a state of vasoconstriction is associated with a first range of blood flow levels and vasodilation is associated with a second range of blood flow levels.

As to claim 9, Kushnir et al. disclose measuring heat transfer (HTD) from a portion of the body as a means to determining the state of vasoconstriction or vasodilation (col. 8, lines 47-62)

As to claim 14, Kushnir et al. disclose measuring bio-impedance (skin conductance) as a means to determining the state of vasoconstriction or vasodilation (col. 8, lines 47-62).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Kushnir et al. in view of Kimball et al. (6,258,046) who disclose that either ultrasound Doppler or laser Doppler can be used interchangeably in the measurement of blood flow and that such a measurement inherently includes measuring the volume of the portion of the body (col. 5, lines 60-col. 6, line 2).

Claim 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kushnir et al.

As to claim 15, this rejection is made in light of the applicant's disclosure, that vasoconstriction or vasodilation can be measured by the well known means using oximetry or light absorption [0027].

As to claims 16 and 17, although Kushnir et al. fail to specifically disclose the combined use of an EKG or an ECG during the procedure or heating/cooling the patient, the examiner maintains that it would have been obvious to a skillful artisan to provide either an EKG or an ECG to so that this combination would assist medical personnel in understanding the patient's condition during the surgery (col. 1, lines 9-42).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kushnir et al. in view of Dae et al. (6,572,638). Kushnir et al. fail to disclose the act of controlling at least one of vasoconstriction or vasodilation includes drug delivery. But, Dae et al. disclose a method of controlling body temperature while inhibiting shivering by injecting drugs to control vasoconstriction (prevent it) when the patient is being cooled (col. 17, lines 28-56). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the method of Kushnir et al., as taught by Dae et al., to control vasoconstriction by drug delivery.

#### ***Allowable Subject Matter***

Claims 29-33 and 43-44 are allowed.

Claims 18, 22-24, 28 and 38-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

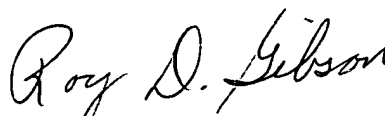
#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Salmon (US 2003/0040783) discloses an apparatus for raising or maintaining the core body temperature; and Salmon et al. (6,719,780) disclose a warming method and apparatus for raising or maintaining the core body temperature during surgery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Roy D. Gibson  
Primary Examiner  
Art Unit 3739

June 21, 2005